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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,171	03/10/2004	Dean E. Cropper	CRP002	3497

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EXAMINER	
PHAM, HUONG Q	

ART UNIT	PAPER NUMBER
3772	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,171	CROPPER, DEAN E.	
	Examiner	Art Unit	
	Huong Q. Pham	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/18/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16, 19-21, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Labour et al (4,445,505).

Labour et al teaches every claimed feature of the claims including an inward elastic tracking member 80 that operatively fits over, and provides inward pressure against, a patella , wherein the inward tracking member 80 is capable of providing a compressive force against the patella. As for claim 16, note that the inward pressure can be applied through an intermitten and progressively increased tightening of the inward tracking member 80 by adjusting the postion of the free end of tracking member 80 relative to member 92(figure 2). As for claim 19, note that the inward tracking member 80 of Labour et al is capable of being adjusted to increase or decrease an amount of inward pressure. As for claims 20-21, note that the inward tracking member is capable of providing continuous compressive force against the patella throughout a full range of extension motion of an associated knee, and wherein the continuous

compressive force can be substantially the same throughout the extension motion. As for claim 26, note that the inward tracking member 80 is an elastic strap.

Claims 1-8, 14- 21, 26- 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehman (3,804,084).

Lehman teaches a medial tracking member 60, 62 operatively fits along a lateral side of, and capable of providing medial traction to, a patella having patellofemoral articular tissue; and an inward tracking member 90 that operatively fits over, and capable of providing inward pressure against, the patella; wherein the inward tracking member 90 is capable of providing a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove. As for claim 2, note that the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member 90. As for claim 3, note that the inward tracking member 90 directly overlays the patella and the medial tracking member 60, 62 so that medial traction can be placed on the patella. As for claim 4, note that the medial tracking member 60, 62 is adjustable to increase or decrease an amount of medial traction. As for claim 5, note that the inward tracking member 90 is adjustable to increase or decrease an amount of inward pressure. As for claim 6, note that the inward tracking member 90 is capable of providing a continuous compressive force against the patella throughout a full range of extension motion of an associated knee. As for claim 7, note that the continuous compressive force can be the same throughout the

extensionmotion. As for claim 8, note that the continuous compressive force increases throughout the extension motion. As for claim 14, note that the inward tracking member 90 comprises an elastic, adjustable strap. As for claims 15-21, and 26, note the comments relative to the claims above. As for claims 27-29, note that the device of Lehman has all structure recited in claims 27- 29; with the medial tracking member 60, 62 and inward tracking member 90 wrapped and secured around the knee in a manner similar to the way applicant's medial tracking member and applicant's inward tracking member 90 are wrapped and secured around a knee; wherein in applying Lehman's device to a wearer, one would perform the steps of applying the medial tracking member 60, 62 that operatively fits along a lateral side of, and in doing so providing certain degree of medial traction to, a patella having patellofemoral articular tissue; and applying an inward tracking member 90 that operatively fits over, and in doing so providing certain degree of inward pressure against, the patella; wherein the inward tracking member 90 would provides certain degree of compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove. As for claim 28, note that if desired by a wearer, when the position of inward tracking member 90 is adjusted, the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member. As for claim 29, note that if desired by a wearer, the medial traction applied through the intermittent and progressively increased tightening of the inward tracking member 90 would increasingly stretch lateral patellar connective tissue over time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 14, 17- 18, 22-25, 27- 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cawley et al (6,551,264) in view of Labour et al (4,445,505).

Cawley et al teaches a knee orthosis comprising a medial tracking member 76, 74, 78, 80 (figure 1) that operatively fits along a lateral side of, and capable of providing medial traction to a patella having patellofemoral adicular tissue. Labour et al teaches medial tracking member 36, 38 in combination with an elastic inward tracking member 80 that operatively fits over, and capable of providing some degree of inward pressure against the patella, wherein the inward tracking member 80 is capable of providing some degree of compressive force against the patella. In view of the teaching of Labour et al, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide an inward tracking member for the device of Cawley et al in order to provides a compressive force against the patella.

As for claim 2, note that the inward pressure 80 of Labour et al is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member 80. As for claim 3, note that the inward tracking member 80 directly overlays the patella and the medial tracking member 36, 38 so that medial

traction can be placed on the patella. As for claim 4, note that the medial tracking member 76, 74, 78, 80 of Cawley et al is adjustable to increase or decrease an amount of medial traction. As for claim 5, note that the inward tracking member 80 of Labour et al is adjustable and therefore is capable of increasing or decreasing some degree of inward pressure. As for claim 6, note that the inward tracking member 80 of Labour et al is capable of providing a continuous compressive force against the patella throughout a full range of extension motion of an associated knee. As for claim 7, note that the continuous compressive force can be the same throughout the extension motion. As for claim 8, note that the continuous compressive force increases throughout the extension motion. As for claims 9-11 , 22-24, note figure 5 of Cawley et al. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable over prior art (for example, note the polycentric hinges of the US patents 4,781,179 and 4,572,170). Note that when providing an inward tracking member to the device of Cawley et al , one ordinary skill in the art would have mounted or attached the inward tracking member to the hinge 42 and /or to the arms 12,14, 16, 18. As for claims 12, 25, note the elastic sleeve 12 of Labour et al , and note the member 44 of Cawley et al. As for claim 13, note the raised spacing member 74 of Cawley et al (figure 1). As for claim 14, note that the inward tracking member 80 of Labour et al comprises an elastic, adjustable strap. As for claims 17-18, note the comments relative to the claims above. As for claims 27-29, note that the device of Cawley et al and Labour et al has all structure recited in claims 27- 29; with the medial tracking member 76, 74, 78, 80 and inward tracking member 80 (taught

by Labour et al as discussed above) wrapped and secured around the knee in a manner similar to the way applicant's medial tracking member and applicant's inward tracking member are wrapped and secured around a knee; wherein in applying Cawley et al and Labour et al's device to a wearer, one would perform the steps of applying the medial tracking member 76,74,78,80 that operatively fits along a lateral side of, and in doing so providing certain degree of medial traction to, a patella having patellofemoral articular tissue; and applying an inward tracking member that operatively fits over, and in doing so providing certain degree of inward pressure against, the patella; wherein the inward tracking member would provides certain degree of compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove. As for claim 28, note that if desired by a wearer, when the position of inward tracking member is adjusted, the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member. As for claim 29, note that if desired by a wearer, the medial traction applied through the intermittent and progressively increased tightening of the inward tracking member would increasingly stretch lateral patellar connective tissue over time.

Claims 9-13, 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehman (3,804,084) in view of Cawley et al (6,551,264).

Note the comments above for the teaching of Lehman. Cawley et al teaches a knee orthosis with bicentric hinge (note figure 5 of Cawley et al) . In view of this

teaching of Cawley et al, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide the device of Lehman with a support having bicentric hinge for stabilizing the knee joint. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable over prior art (for example, note the polycentric hinges of the US patents 4,781,179 and 4,572,170). Providing the device of Lehman and Cawley et al as discussed above, note that one ordinary skill in the art would have mounted or attached the inward tracking member 90 on or to the polycentric hinge .

Applicant's arguments filed on 9/18/2006 have been fully considered but they are not persuasive.

Applicant argues that in Labour et al , the patella is nested and thus protected from inward tracking by the opening 30 . The examiner does not agree. Note that column 3, lines 3-6 of Labour et al states that " The opening 30 relieves pressure against the patella, prevents abrasion of the skin during vigorous activity of the patient , and increases the flexibility of the brace at the patella. Note that this particular sentence in the Labour et al refers to the purpose of the patella cut out or opening 30 in the elastic sleeve 12. Note that the provision of a patella cut out or opening 30 in a sleeve for the purpose of preventing abrasion of the skin because of the friction between the wearer's patella area and the sleeve of the brace during vigorous activity of the patient , and for the purpose of increasing the flexibility of the brace at the patella is very well known in the art. However, in combination with providing the patella opening for the

purpose discussed above, Labour et al also provides inward tracking member 80 so that when the inward tracking member 80 is pulled tight across the front of the sleeve, the inward tracking member 80 prevents anterior displacement of the patella through the opening (column 4, lines 30- 49). This means that the inward tracking member 80 provides some degree of compressive pressure against the patella in order to prevent anterior displacement of the patella through the opening . Note that inward tracking member 80 also applies pressure to the pad 36 so as to create an effective barrier to prevent lateral displacement of the patella). Applicant argues that "the neoprene fabric mostly used as the elastisized fabric in Labour's brace.....", and " the fabric used at the time of Labour is too thick for the strap 80 to provide inward tracking"... The examiner does not agree. Note in column 2 of Labour et al , lines 45-50 that sleeve 12 is preferably is knitted of a soft cotton yarn an elasticized thread so as to be comfortable on the body. Applicant argues that strap 80 of Labour et al is too short and too wide inward tracking of the patella. Note that the strap 80 is long enough and wide enough to provide the inward tracking function as recited in the claims. It appears that applicant 's inward tracking member shown in figure 1 is just about as wide as the inward tracking member 80 of Labour et al. Applicant argues that " increased tightening of adjustable strap 80 would have the opposite effect of inward force so that such action would in effect tend to push the patella outwardly and away from the trochlear groove.....". The examiner does not agree. Note that the 2 functions of strap 80, when pulled tight across the front of the sleeve as in figure 2, is to : 1) apply pressure to the pad 36 to prevent lateral displacement of the patella, and to : 2)prevents anterior displacement of

the patella through the opening (by applying some degree of inward compressive force against the patella).

Applicant argues that Lehman's strip 90 is not an inward tracking member... , and that " the circumferential force of a tightened strap compresses only the raised portions that lie around the perimeter of the patella, and not the patella", and " increased tightening of adjustable strip 90 would have the opposite effect of inward force so that such action would in effect tend to push the patella outwardly and away from the trochlear groove ....". The examiner does not agree. Note in figure 4 of Lehman that when the strip 90 compresses members 60, 62, 50, 52, thereby squeezes the area surrounding the patella, similar to the strap 80 of Labour et al, the 2nd function of the strip 90 is to provide some degree of inward compressive force against the patella in order to prevent the patella to be pushed outwardly by members 60,62, 50,52.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q. Pham whose telephone number is (571) 272-4980. The examiner can normally be reached on 8:45 AM - 5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272 - 4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael A. Brown

November 21, 2006

MICHAEL A. BROWN
PRIMARY EXAMINER